

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in March 2006.

New Approvals

NADA Number: 100-094

Trade Name: PoultrySulfa™
Ingredients: Sulfamethazine, sulfamerazine, sulfaquinoxaline
Sponsor: Alpharma Inc.
Approval Date: February 2, 2006
Status: Over-the-counter
Route: Oral
Species: Chickens and turkeys
Drug Form: Powder (soluble)
Concentration: 78 grams sulfamerazine, 78 grams sulfamethazine, and 39 grams sulfaquinoxaline per packet.
Indications: **Turkeys and Chickens:** As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamethazine, sulfamerazine, and sulfaquinoxaline.
Turkeys: As an aid in the control of coccidiosis caused by *Eimeria meleagriditis* and *E. adenoides* susceptible to sulfamethazine, sulfamerazine, and sulfaquinoxaline.
Chickens: As an aid in the control of coccidiosis caused by *Eimeria tenella* and *E. necatrix* susceptible to sulfamethazine, sulfamerazine, and sulfaquinoxaline.
Tolerance: Sulfamerazine – A tolerance for residues in chicken and turkey tissues is not established at this time.
21 CFR 556.670 Sulfamethazine: A tolerance of 0.1 part per million is established for negligible residues of sulfamethazine in the uncooked edible tissues of chickens and turkeys.
21 CFR 556.685 Sulfaquinoxaline: A tolerance of 0.1 part per million is established for negligible residues of sulfaquinoxaline in the uncooked edible tissues of chickens and turkeys.
Withdrawal: 14 days

21CFR 520.2218

ANADA Number: 200-387

Pioneer Product: 101-479
Trade Name: Flunazine™
Ingredients: Flunixin meglumine
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: March 2, 2006
Status: Prescription only
Route: Intravenous, intramuscular
Species: Horse and cattle
Drug Form: Liquid
Concentration: 50 milligrams per milliliter
Indications: **Horse:** For the alleviation of inflammation and pain associated with musculoskeletal disorders. It is also recommended for the alleviation of visceral pain associated with colic.
Cattle: For the control of pyrexia associated with bovine respiratory disease and endotoxemia. Also, for the control of inflammation in endotoxemia.
Tolerance: 21 CFR 556.286: Flunixin – The tolerance in cattle for flunixin free acid the (marker residue) is 125 parts per billion in the liver (target tissue), 25 parts per billion in the muscle, and 2 parts per billion in milk.
Withdrawal: Cattle: Meat - 4 days, milk – 36 hours

21CFR 522.970

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Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-308

Trade Name: Flunixin Injection
Ingredients: Flunixin meglumine
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: March 1, 2006

This application provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia and for the control of inflammation in endotoxemia.

21CFR 522.970

NADA Number: 141-081

Trade Name: Orbax®
Ingredients: Orbifloxacin
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: March 3, 2006

This application provides for revised safety labeling.

21CFR 520.1616

Change of Sponsor's Drug Labeler Code

Med-Pharmex, Inc.
2727 Thompson Creek Rd.
Pomona, CA 91767-1861
Drug Labeler code: 054925

Addition of Patent Number(s)

NADA Number(s): 141-238 & 141-239

Patent Number: 4,902,683
Expiration Date: May 25, 2008

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number: 06P-0093/CP1
Sponsor: ECO Animal Health
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® 1%, Merial Ltd., NADA 128-409, by the following characteristic(s): The generic will differ in strength (2%) from the pioneer product (1%).
Action: Filed March 1, 2006.

Correction of Patent Information

NADA Number: 141-080

Patent Numbers: 5,192,808 Expiration Date: May 30, 2011

NADA Number: 141-082

Patent Numbers: 5,324,519 Expiration Date: June 28, 2011

NADA Number: 141-151

Patent Numbers: 4,801,584 Expiration Date: September 8, 2007
4,864,023 September 8, 2007

NADA Number: 141-199

Patent Numbers: 4,882,164 Expiration Date: January 19, 2008

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of drug labeler code for Med-Pharmex, Inc. This rule is effective March 16, 2006. The new drug labeler code for Med-Pharmex, Inc. is 054925.

FDA has found that the animal drug regulations do not reflect the correct drug labeler code for Med-Pharmex, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600, 520.1044a, 520.1195, 520.1484, 520.1485, 520.2220a, 520.2345d, 522.900, 524.1044b, 524.1044f, 524.1044g, 524.1193, 524.1443, 524.1580b, 524.1580e, 524.1600a, 524.2481, and 529.1044b to correct this error. In addition, 21 CFR 524.1044b, 524.1044f, 524.1443, and 524.2481 are being revised to reflect a current format.

For further information contact: Charles Eastin, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9077, e-mail: charles.eastin@fda.hhs.gov.

Actions Taken by FDA Center for Veterinary Medicine

Final Rules & Notice(s)

The Food and Drug Administration (FDA) is issuing an order prohibiting the extralabel use of anti-influenza adamantane and neuraminidase inhibitor drugs in chickens, turkeys, and ducks. We are issuing this order based on evidence that extralabel use of these anti-influenza drugs in chickens, turkeys, and ducks will likely cause an adverse event in humans.

This rule becomes effective June 20, 2006. Submit written or electronic comments on this document by May 22, 2006.

You may submit comments, identified by Docket No 2006N-0106, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following ways: Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Written Submissions: Submit written submissions in the following ways: FAX: 301-827-6870. Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph. Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document, March 22, 2006. Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), 2006N-0106, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For further information contact: Kim Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9207, e-mail: kim.young@fda.hhs.gov.

The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

We welcome general comments on this list and on agency guidance documents at any time.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. For information on a specific guidance or to obtain a hard copy of any of the guidances currently in use, contact the appropriate Center in the SUPPLEMENTARY INFORMATION section of this notice, March 28, 2006.

For further information contact: Regarding GGPs: Lisa Helmanis, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3480.

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of four supplemental new animal drug applications (NADAs) filed by Phibro Animal Health. One supplemental NADA provides for the use of fixed-combination Type A medicated articles containing oxytetracycline and neomycin sulfate to formulate two-way fixed-combination drug Type B and Type C medicated feeds for chickens, turkeys, swine, cattle, and sheep. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing nicarbazin and penicillin, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for broiler chickens. The fourth supplemental NADA provides for the use of approved, single-ingredient Type A medicated articles containing nicarbazin, bacitracin methylene disalicylate, and roxarsone to formulate three-way combination drug Type C medicated feeds for broiler chickens. These approvals reflect FDA's effectiveness conclusions which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

This rule is effective March 31, 2006.

Actions Taken by FDA Center for Veterinary Medicine

For further information contact: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-50), 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: andrew.beaulieu@fda.hhs.gov.

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of three supplemental new animal drug applications (NADAs) filed by Alpharma, Inc. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing bacitracin methylene disalicylate and zoalene, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for replacement chickens. The third NADA provides for the use of bacitracin zinc and nitarsone single-ingredient Type A medicated articles for two-way combination Type C medicated feeds for growing turkeys. These approvals reflect FDA's effectiveness conclusions, which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

This rule is effective March 31, 2006.

For further information contact: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-50), 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: andrew.beaulieu@fda.hhs.gov.

The Food and Drug Administration (FDA) is removing regulations that exempted certain new animal drugs administered in feed from batch certification requirements. FDA is also removing portions of a regulation that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofurans, and sulfonamide drugs administered in animal feed. The intended effect of this rule is to remove regulations that are obsolete or redundant. The portions of the latter regulation that are being removed are most of the Type A medicated articles and use combinations that are listed in the tables contained in that regulation. This rule does not finalize the provisions of the proposed rule regarding removing the remainder of that regulation.

This rule is effective May 1, 2006.

For further information contact: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-50), 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, email: andrew.beaulieu@fda.hhs.gov.